UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/651,528	08/29/2003	Kristin Monday	KM--001	8870

7590 03/17/2008

STEVEN SHATTIL
P. O. BOX 17355
BOULDER, CO 80308-0355

EXAMINER	
WINSTON, RANDALL O	
ART UNIT	PAPER NUMBER
1655	
MAIL DATE	DELIVERY MODE
03/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/651,528	MONDAY, KRISTIN	
	Examiner	Art Unit	
	RANDALL WINSTON	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *10-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made of receipt and entry of the amendment filed on 12/26/2008.

Applicant's amendment has overcome Examiner's 112, second paragraph, rejection.

Examiner's acknowledges that claims 10-18 have been withdrawn by consideration.

Claims 1-9 will be examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recite the limitation "the glandular agent." There is insufficient antecedent basis for the limitation as claimed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 as amended stand rejected under 35 USC 112, first paragraph, for the reasons set forth in the previous Office action which are restated below.

Claims 1-9 as amended stand rejected under 35 USC 112, first paragraph, because one can not extrapolate the teaching of the specification to the claimed invention because there is no guidance on or exemplification in the specification to prepare a composition comprising a first component containing Gonadotrophin-releasing hormone; a second component comprising a kelp; and a third component comprising prolactin to increase breast size in a subject. The specification does not enable any person skilled in the art to which it pertains, or with which is most nearly connected, to make and/or use the invention commensurate in scope with the claims.

The factors to be considered in determining whether undue experimentation is required are summarized in In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; © the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Applicant claims a composition comprising a first component containing Gonadotrophin-releasing hormone; a second component comprising a kelp; and a third component comprising prolactin to increase breast size in a subject. Applicant's specification, however, failed to provide any guidance or any working examples whereby applicant has prepared a composition comprising a first component containing Gonadotrophin-releasing hormone; a second component comprising a kelp; and a third component comprising prolactin to increase breast size in a subject.

Furthermore, it is noted that the state of the prior art at the time the invention was filed did not recognize a composition comprising a first component containing Gonadotrophin-releasing hormone; a second component comprising a kelp; and a third component comprising prolactin to increase breast size in a subject nor did the state of the prior art at the time the invention was filed did not recognize each individual claimed active ingredient within the claimed composition of increasing breast size in a subject. For example, Civelli et al. teach (US 6383764, see, e.g. entire patent, especially claims), that a prolactin releasing peptides of the pituitary controls absence seizures. Furthermore, Fleischner teaches (US 6503529, see, e.g. column 7 lines 46-53) bladderwrack kelp is used as a dietary supplement to regulate thyroid functions. Thus, the art is silent regarding the efficacy of applicant's composition comprising a first component containing Gonadotrophin-releasing hormone; a second component comprising a kelp; and a third component comprising prolactin to increase breast size in a subject. Therefore, applicant's claimed composition comprising a first component containing Gonadotrophin-releasing hormone; a second component comprising a kelp; and a third component comprising prolactin to increase breast size in a subject is unpredictable in the art.

Thus, per reference to the Wands factors, due to the state of the prior art at the time the invention was filed did not recognize the claimed composition as being used to increase breast size in a subject as taught by Civelli and Fleischer thus rendering the claimed composition as being unpredictable in the art and due to applicant's specification failing to provide any guidance or working examples whereby applicant has

prepared a claimed composition used to increase breast size in a subject and due to the large quantity of experimentation necessary to demonstrate the claimed composition as being used to increase breast size in a subject, it would require undue experimentation without a reasonable expectation of success for one of skill in the art to practice the invention commensurate in scope of the claims.

Applicant's arguments have been carefully considered but they are not deemed persuasive. Applicant argues that the specification does enable any person skilled in the art to which it pertains, or with which is most nearly connected, to make and/or or use the invention commensurate in scope with the claims. Applicant states that the specification teaches an embodiment having specific amounts of each component: "the composition comprises 75-90% by weight a glandular agent, 5-24% by weight a pituitary extract, and 1-5% by weight a kelp derivative." Furthermore, Applicant argues the state of the prior art does, in fact, describe the efficacy of each of the claimed components for increasing breast size.

Although Applicant argues that the specification in paragraph 10 teaches an embodiment having specific amounts of each component, Applicant argument is not found persuasive because Applicant has failed to provide the Examiner an adequate written description of the claimed invention. Applicant's specification has failed to provide the Examiner with any guidance or working examples of the claimed invention whereby applicant has prepared a composition comprising a first component containing

Gonadotrophin-releasing hormone; a second component comprising a kelp; and a third component comprising prolactin to increase breast size in a subject.

Moreover, Although Applicant argues the state of the prior art does, in fact, describe the efficacy of each of the claimed components for increasing breast size, Applicant argument is not found persuasive because Applicant still maintains that the state of the prior art at the time the invention was filed did not expressly recognize each individual claimed active ingredient within the claimed composition of increasing breast size in a subject. For example, Civelli et al. expressly teach (US 6383764, see, e.g. entire patent, especially claims), that a prolactin releasing peptides of the pituitary controls absence seizures. Furthermore, Fleischner expressly teaches (US 6503529, see, e.g. column 7 lines 46-53) bladderwrack kelp is used as a dietary supplement to regulate thyroid functions. Thus, the art is silent regarding the efficacy of applicant's composition comprising a first component containing Gonadotrophin-releasing hormone; a second component comprising a kelp; and a third component comprising prolactin to increase breast size in a subject. Therefore, applicant's claimed composition comprising a first component containing Gonadotrophin-releasing hormone; a second component comprising a kelp; and a third component comprising prolactin to increase breast is unpredictable in the art.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RANDALL WINSTON whose telephone number is (571)272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher R. Tate/
Primary Examiner, Art Unit 1655